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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,239	07/17/2003	Anthony L. Fitzhugh	14364.99	8121

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MEDTRONIC VASCULAR, INC.  
IP LEGAL DEPARTMENT  
3576 UNOCAL PLACE  
SANTA ROSA, CA 95403

EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/623,239	<b>Applicant(s)</b> FITZHUGH ET AL.	
	<b>Examiner</b> Blessing M. Fubara	<b>Art Unit</b> 1618	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10/18/05.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-26 and 33-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) 1-26 and 33-47 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Examiner acknowledges receipt of amendment and remarks filed 10/18/05. Claims 1-26 and 33-44 and new claims 45-47 are pending.

#### *Claim Rejections - 35 USC § 112*

1. The rejection of claim 34 under 35 U.S.C. 112, first paragraph, is withdrawn in light of the amendment to claim 34.

#### *Claim Rejections - 35 USC § 102*

2. Claims 1, 2, 5 and 23-26 remain rejected under 35 U.S.C. 102(b) as being anticipated by Pulfer et al. (Incorporation of Nitric Oxide-Releasing Crosslinked polyethyleneimine Microspheres Into Vascular Grafts; Journal of Biomedical Materials Research; Wiley, New York, NY, Vol. 37, No. 2, November 1997; pp 182-189).

Applicants argue that Pulfer does not disclose the characteristics of highly cross-linked and highly hydrophobic substances; that the instant specification at paragraph 48, pages 21 and 22 define the term highly cross-linked as being 'consistent with its ordinary meaning as understood by persons skilled in the art of synthetic organic chemistry.

Therefore, as used in the present invention, the term "highly cross-linked" is defined as a polymer substrate having an extensive network of primary chemical bonds linking the individual monomers together such that the polymer is essentially bound into a single molecule. This definition is not inconsistent with the general understanding of the "highly-cross-linked." For example, and not intended as a limitation, when divinylbenzene (DVB) is used to form the polymer beads of the present invention, the

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individual monomers of DVB become linked together (polymerized) by interactions between vinyl groups on neighboring DVB molecules. As the polymer chain grows additional polymerization reactions occur within the polymer chain resulting in a cross-linked matrix. The more extensive these additional interactions are, the more highly cross-linked the polymer becomes.’ Furthermore, the specification defines extreme hydrophobicity as ‘extreme hydrophobicity of its divinylbenzene substituents prevents such a polymer from swelling when immersed in aqueous solutions such as physiological or bodily fluids. While not wishing to be bound by any particular theory, it is believed that in non- or poorly cross-linked diazeniumdiolated hydrophobic polymers of the type disclosed in the prior art and in the '919 patent, the intrusion of water and other protonating species into the interior of the polymer causes it to rapidly swell. As large hydrophilic channels are created, the protonation of sequestered diazeniumdiolate groups within the polymer is facilitated and there is a corresponding liberation of NO from the polymer.’

3. Applicants' arguments filed 10/18/05 have been fully considered but they are not persuasive.

The scope of “highly cross-linked” and “extremely hydrophobic” permits the application of the teachings of the prior art. While applicants cite the specification as defining “highly cross-linked” and “extremely hydrophobic” to be consistent with ordinary meaning, the scope of “consistent with ordinary meaning” is not inventive over the interpretation of the cross-linked and hydrophobic polymer. The prior art uses the polymer for the same purposes as the instant polymer. There is no factual evidence of unexpected result of “highly cross-linked” and

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“extremely hydrophobic” over cross-linked and hydrophobic polymer. Thus each and every element is taught by the prior art. And “when the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

***Claim Rejections - 35 USC § 103***

4. Claims 3, 4, 6-22 and 33-~~47~~ remain rejected under 35 U.S.C. 103(a) as being unpatentable over Pulfer et al. (Incorporation of Nitric Oxide-Releasing Crosslinked polyethyleneimine Microspheres Into Vascular Grafts; Journal of Biomedical Materials Research; Wiley, New York, NY, Vol. 37, No. 2, November 1997; pp 182-189). New claims 45-47 are included in the rejection and this rejection is necessitated by the addition of the new claims.

Applicants argue that Pulfer does not disclose “highly cross-linked” and “extremely hydrophobic nitric oxide releasing polymer” and, although, applicants agree with examiner that “highly cross-linked” and “extremely hydrophobic” are relative terms, an express disclosure of the “highly cross-linked” and “extremely hydrophobic” is required to maintain the rejection.

5. Applicants' arguments filed 10/18/05 have been fully considered but they are not persuasive.

Examiner acknowledges applicants' admission that “highly cross-linked” and “extremely hydrophobic” are relative terms. The scope of the relativeness of the “highly cross-linked” and “extremely hydrophobic” permit the application of the teachings of the prior art. The prior art

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uses the cross-linked and hydrophobic polymer for the same purposes that the “highly cross-linked” and “extremely hydrophobic” polymer of the instant claims is used for. There is no demonstration of unexpected/unusual results and in the absence of factual evidence, the instant “highly cross-linked” and “extremely hydrophobic” polymer is not inventive over the cross-linked and hydrophobic polymer of the prior art, whose purpose/function is the same as that of the instant claimed polymer.

### ***Claim Objections***

6. The objection of claims 9-13 under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is withdrawn in light of the amendment.

Examiner further acknowledges applicants reference to the ‘666 patent.’

No claim is allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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